HFA-305

Approval letter dated NOV 1 9 2002

FREEDOM OF INFORMATION SUMMARY

EB 19 7.5.0.A

# SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

**ANADA 200-123** 

MAXIM-200® Injection

"addition for use in lactating dairy cattle"

Sponsored by:

Phoenix Scientific, Inc. St. Joseph, MO 64503

# FREEDOM OF INFORMATION SUMMARY GENERAL INFORMATION:

ANADA Number:

200-123

Sponsor:

1.

Phoenix Scientific, Inc. 3915 S. 48<sup>th</sup> St. Terrace St. Joseph, MO 64503

Drug Labeler Code: 059130

Generic Name:

Oxytetracycline Hydrochloride, USP

Pioneer Product:

Pfizer, Inc., Liquamycin® LA-200

NADA 113-232

Trade Name:

MAXIM-200® Injection

Dosage Form:

Injectable

Effect of Supplement:

The supplement provides for use in lactating dairy

cattle.

Route of Administration:

Intramuscular in swine, Intramuscular, Intravenous, and Subcutaneous in cattle

Dosage & Indications for Use:

<u>Cattle: Beef and dairy, calves including pre-</u>ruminating veal calves.

For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

# Swine:

For the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, it is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli* 

Dosage For Cattle: 3-5 mg/lb body weight IM, SC, or IV once daily for up to 4 days, or 9 mg/lb IM or SC as a single dose.

Dosage For Swine: 3-5 mg/lb body weight IM daily, or 9 mg/lb IM as a single dose.

# 2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, MAXIM-200® Injection was granted a waiver on October 22, 1993, from conducting an *in vivo* bioequivalence study. The abbreviated new animal drug application was approved on February 10, 1995. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

## 3. HUMAN SAFETY

The previous withdrawal periods and tolerances remain unchanged. Therefore, no human food safety information is required.

Withdrawal periods: Cattle & Swine 28 days

## **REGULATORY METHOD:**

The regulatory method for determination of oxytetracycline in tissues is a microbiological assay procedure using *Bacillus cereus* var. *mycoides* (ATCC 11778) suspension and is found in the FDA publication "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols" revised October 1968, reprinted December 1974. (Available from the FDA, Center for Veterinary Medicine, 7500 Standish Place, Rockville, Maryland 20855.)

# 4. AGENCY CONCLUSIONS:

This Supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal Food, Drug and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that MAXIM-200® Injection is safe and effective for its labeled indications, when used under its proposed conditions of use.

# 5. LABELING:

Attachments:

Generic Labeling:

Package Insert

100, 250, & 500 mL bottles

Pioneer Labeling: Package Insert

100, 250, & 500 mL bottles

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration Freedom of Information Staff (HFI-35) 5600 Fishers Lane Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

cc: HFV-199 ANADA 200-123 C-0032

HFV-2 Special Mailing List

HFV-12 FOI Staff

HFV-107 Green Book (N. Turner)

HFV-107 QAT Reserve Copy

HFV-104 GADT copy

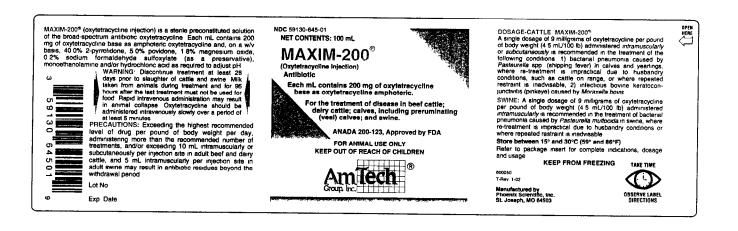
HFV-120 Labeling Project (P. Ryan)

HFA-305 Dockets Management Branch

HFR-SW 350, KAN-DO

Courtesy Copy for Sponsor

ec: CVM Records\ONADE\\A200123\C0032FOI.SUM



Pantone 1797 & Black



MAXIM-200® (oxytetracycline injection) is a sterile preconstituted solution of the broad-spectrum antibotic oxytetracycline Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline and, on a w/v basis, 400% 2-pyrrolidone, 5.0% povidone, 18% magnesium oxide, 0.2% sodium formaldehyde sulloxyfate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pt.

WARNING: Discontinue treatment at least 28 days pnor to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the least treatment must not be used for food Hapid intravenous administration may result in animal collapse Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes.

PRECAUTIONS: Exceeding the highest recommended level of drug per pound of body weight per day, administering more than the recommended number of

treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine may result in antiblotic residues beyond the withdrawal period.

T-Rev. 1-02

600050

Lot No.

Exp Date

NDC 59130-645-02

NET CONTENTS: 250 mL

# MAXIM-200® (Oxytetracycline Injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as oxytetracycline amphoteric.

For the treatment of disease in beef cattle; dairy cattle; catves, including preruminating (veal) calves; and swine.

ANADA 200-123, Approved by FDA

FOR ANIMAL USE ONLY KEEP OUT OF REACH OF CHILDREN



DOSAGE-CATTLE: MAXIM-2000

A single dosage of 9 milligrams of oxyetracycline per pound of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions. 1) bacteral pneumonia caused by Pasteurella spp. (shipping fever) in calves and yearings, where re-treatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by Moraxella bovis

SWINE: A single dosage of 9 milligrams of oxytetracycline per pound of body weight (4.5 mL/100 bi) administered intranscularly is recommended in the treatment of bacterial pneumonia caused by Pasteurella multocida in swine, where re-treatment is impractical due to husbandry conditions or where repeated restrant is inadvisable.

Store between 15° and 30°C (59° and 86°F)
Refer to package insert for complete indications, dosage and usage

KEEP FROM FREEZING

TARE TIME C. DIRECTIONS

Manufactured by Phoenix Scientific, Inc St Joseph, MO 64503

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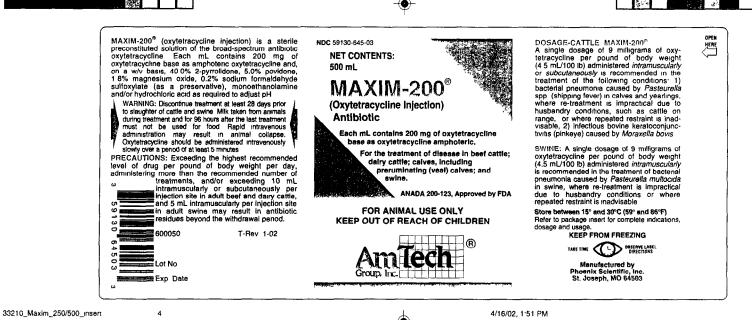
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Pantone 1797 & Black



#### Entering the Vein and Making the Injection

- 1 Raise the vein. This is accomplished by lying the choke rope tightly around the neck close to the shoulder. The rope should. be fied in such a way that it will not come loose and so that it can be unfied quickly by pulling the loose end (See Fig. II) in thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the beart. Under ordinary conditions if cannot be seen or felt with the lingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently fight, the year stands out and can be easily seen and felt in thin-necked animals. As a further check in identifying the vein Tap it with the fingers in front of the choke rope Pulsations that can be seen or fell with the fingers in front of the point being tapped will confirm the fact that the vein is properly distended. It is Impossible to put the needle into the vein unless it is distended. Experienced operators are able to raise the vein simply by hand pressure, but the use of a choke rope is more certain
- 2 inserting the needle. This twolves three distinct steps First, insert the needle through the hole Second, insert the needle into the ven This may require two or three altempts before the venn is entered. The ven has a henderly to foll away the henderly, especially if the needle is not sharp. The ven can be steaded with the themsh and finger of one hard. With the other hand, the needle point is placed directly over the ven stanting it so that its direction is along the length of the vern either toward the head or toward the hear! Properly positioned this way, a quick thrust of the needle, which indicates that the ven has been entered. Third, once in like ven in the needle should be inserted along the length of the ven all the way to the high exercising caultion to see that the ven all the way to the high exercising caultion to see that the

needle does not penerate the opposite side of the ven Continuous steady flow of blood through the needle indicates that the needle is still in the vein. It blood does not flow continuously, the needle is out of the veln for clogged) and another attempt must be made if difficulty is encountered, it may be advisable to use the vein on the other side of the needle.

- 3 While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that the injection can be started without delay after the vein has been entered.
- 4 Making the injection. With the needle in position as indicated by continuous flow of blood, release the choke rope by a quick pull on the free off This is essential: I the medication cannot flow into the vein white it is blocked immediately connect the syringe containing MAXIMA-200 (oxytetracycline injection) to the needle and slowly depress the plunger. If I there is resistance to operassion of the plunger, this indicates that the needle has slipped out of the vein (or is clogged) and the procedure will have to be repeated. Watch for any swelling under the skin near the needle which would indicate that the medication is not going into the vein Should this occur, it is best for type vein on the googsets suite of the next of the state of the state of the vein on the googsets suite of the next of the state of
- 5 Removing the needle When injection is complete remove needle with straight pull. Then apply pressure over the area of injection momentarily to control any bleeding through needle puncture, using control snaked in alcohol or other suitable antiseptic.

LIVESTOCK DRUG, NOT FOR HUMAN USE RESTRICTED DRUG (Galifornia), USE ONLY AS DIRECTED

600050 T-Rev 1-02

#### DOSAGE-CATTLE: MAXIM-200°

A single dosage of 9 milligrams of oxytetracycline per pound of body weight (45 mJ/100 lb) administered intramuscularly or subculaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by Pasteurella spp (shipping fever) in calves and yearlings, where re-treatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable. 2) infectious bovine keratoconjunctivitis (pinkeye) caused by Moraxella bovis

SWINE: A single dosage of 9 milligrams of oxytetracycline per pound of body weight (45 mt/100 lb) administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by Pasteurella multocida in swine, where re-treatment is impractical due to husbandry conditions or where repeated restrant is inadvisable

Store between 15° and 30°C (59° and 86°F) Refer to package insert for complete indications, dosage and usage

KEEP FROM FREEZING

TAKE TIME US OBSERVE LABEL OTRECTIONS

Manufactured by Phoenix Scientific, Inc. St Joseph, MO 64503 ANADA 200-123, Approved by FDA

#### MAXIM-200® (oxytetracycline Injection) Antibiotic

Each mL contains 200 mg of oxyletracycline base as oxyletracycline ampholeric

For Use in Beet Cattle,
Darry Cattle, Calves, including preruminating
(Veal) Calves, and Swine

READ ENTIRE BROCHURE CAREFULLY
BEFORE USING THIS PRODUCT

MAXIM-200° (oxyletracycline injection) is a sterile, ready-touse solution for the administration of the broad-spectrum antibiotic oxyletracycline by injection Oxyletracycline is an antimicrobial agent that is effective in the treatment of a wide range of diseases caused by susceptible gram-positive and name-neative bacteria.

many or observed sections of s

CAUTION When administered to callle, muscle discoloration may necessitate frimming of the injection site(s) and surrounding lissues during the dressing procedure.

WARNING: Oscontinue trealment at least 28 days prior to staughter of cattle and swine. Mirk taken from animasis during treatment and for 96 hours after the last treatment must not be used for load. Rapid intravenous administration may result in animal collapse. Oxyletracycline should be administered intravenously slowly over a period of at least 5 minutes. PRECAUTIONS Exceeding the highest recommended dosade level of drug per print of body weight per day administering more than the recommended number of treatments and/or exceeding 10 ml. Inframiscularly or suberdaneously per injection site in adult bed and darty cattle and 5 ml. inframiscularly per injection site in adult bed and site manifesting the substitution site in adult bed approved. Consult with your vedermant prior to administering this

Consull with your velorination prior to administering this product in order to determine the propost realment required in the event of an adverse reaction. At the flust sign of any adverse reaction discontinue use of product and seet the advice of your velorination. Some of the reactions may be altifulded either to anaphylaxis (an allergic reaction) or to carchovascular collapse of whomom rains.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved in immune this occurrence, it is recommended that MAXIM-200 be administered slowly by this route. Shortly alter injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antihotic preparations, use of the drug may result in overgrowth of nonsisceptible organisms, including linigh A lack of response by the treated animal, or the development of new srighs may suggest that an overgrowth of nonsisceptible organisms has occurred. If any of these conditions occur, consult and the consultance of the consultanc

Since bacterioslatic drugs may interfere with the bacterioidal action of penicillin it is advisable to avoid giving MAXIM-200 in conjunction with penicillin

STORAGE Store between 15° and 30°C (59° and 86°F), Keen from freezing

ADVERSE REACTIONS Reports of adverse reactions associated with oxyletracycline administration include injection site swelling of resilessness a dava, tembling swelling of eyelfds ears muzzle amus and vulva (or scrotum and sheath in males).



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respiratory abnormalities (labored breathing) frolling at the mouth, collapse and possibly death. Some of these reactions may be all industed either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

#### CARE OF SICK ANIMALS

The use of antibotics in the management of diseases is based on a accurate diagnosis and adequate course of treatment. When properly used in the I teatment of diseases caused by oxytetiacychine-susceptible organisms, norsi animals that his oxytetiacycline injection show a notinceable improvement within 24 to 48 hours. It is recommended that the diagnosis and reterment of animal diseases be carried out by a veterinarian. Since many diseases book alike but require different hypes of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs and needless losses Good housing, annation and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased numbers.

#### INDICATIONS

MAXIM-200 is intended for use in the freatment of the following diseases in beef callfe dairy callfe, cafves, including preruminating (veal) calves, and swine when due to payletracycline-susceptible organisms.

#### CATTLE

In calls: MAXIM-200 is indicated in the treatment of pneumonia and shipping lever complex associated with Pasteurella spip and Hemophilus spip intellious bowine teraloconjuncturitist (pinkeye) caused by Morazella bows, loot-ful and diphtheria caused by Eschenchia coli, wooden tongue caused by Actinobacillus intelligencies, lepioporga poman and wound infections and acute melritist caused by stans of staphylococci and streetopocci organisms ensishing to payelfarcheria.

#### SWINE

In swine, MAXIM-200 (oxyletracycline injection) is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by Escherichia coli, pneumonia caused by Pasleurella multiocida, and leptosolirosis caused by Leptosoria pomona.

In sows MAXIM-200 is indicated as an aid in the control of infectious enteritis (baby pig scours collaborilosis) in suckling pigs caused by Escherichia coli

#### DOSAGE

#### CATTLE

MAXIM-200 is to be administered by inframuscular, subcutaneous or intravenous injection to beet catile, dairy calite, and calves, including preuminating (yeal) calves

A single dosage of 9 milligrams of MAXIM-200 per pound of body weight administered intermuscularly or subcultaneously is recommended in the treatment of the following conditions: 1) bacteral pneumonas caused by Pasteurella spp (shipping lever) in calves and yearlings, where it-realment is simpactical due to husbandry conditions, such as cattle on range, or where their repeated restraint is linadvisable, 2) infectious bovine keratoconjunctivis (pinkeye) caused by Morazella bovis

MAXIM-200 can also be administered by intravenous, subculianeous or intravenous aubculianeous or intravenous and a level of 3 to 5 milligrams of onyletracycline per pound of body velopit per day in the treatment of severe foot-rol and advanced cases of other indicated disseas, dosage level of 5 milligrams per pound of body weight per day is recommended. Treatment should be continued 24 to 48 hours following remission of disease signs, however, not be exceed a told at 0 four consecutive days Consult your veterinarian if improvement is not noted within 24 to 48 hours of the bedoming of treatment.

#### SWINE

In swine a single dosage of 9 milligrams of MAXIM-200 per pound of hody weight administered <u>inframuscularly</u> is recommended in the trealment of bacterial pneumonia caused by *Pasteurella* 

multocida in swine, where re-liealment is impractical due to husbandry conditions or where repeated restraint is finadvisable MAXIM-200 can also be administered by inframuscular injection at a level of 3 to 5 milligrams of oxyletracycline per pound of body weight per day Trealment should be conhumed 24 to 48 hours

at a seed of 3 of 3 minigralish of overleady-one per pound or body weight per day Treatment should be continued 24 to 48 hours following remission of disease signs, however not to exceed a total of four consecutive days. Consult your veterinarism if improvement is not noted within 24 to 48 hours of the beginning of treatment.

For sows administer once inframuscularly 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing

For sivine weighing 25 ib of body weight and under, MAXIM-200 should be administered undituted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 to 5 mg/lb body weight

9 mg/lb DOSAGE		3 OR 5 mg/lb DOSAGE		
Volume of UNDILUTED		Volume of DILUTED		
MAXIM-200		MAXIM-200		
Body Weight	9 mg/lb	3 mg/lb	Dilution	5 mg/1t
5 lb	0 2 mL	0 6 mL	17	1 0 ml
10 lb	0 5 ml	0 9 mL	15	1 5 ml
25 th	1.1 ml	1.5 ml	13	2.5 ml

\* To prepare dilutions, add one part MAXIM-200 to three live or seven parts of sterile water or 5 percent dextrose solution as indicated, the diluted product should be used immediately

#### DIRECTIONS FOR USE

MAXIM-200 is miended for use in the treatment of disease due to oxyletracycline-issocephible organisms fine bet callle, dany callle, calves including percentrating reveral calves; and swine A inbroughly cleaned, sterite needle and syrings should be used for each neption (redelles and syrings may be settinized by botting in water for 15 minutes). In cold weather, MAXIM-200 should be warmed to room temperature before administration to animals. Before withframing the solution forms the bottle, disnatic the trobber.

cap on the bottle with suitable disinfectant such as 70 percent alcohol. The injection site should be similarly cleaned with the disinfectant Needles of 16 to 18 gauge and 1 to 1 1/2 inches tong are adoquate for inframuscular or subculaneous injections. Needles 2 to 3 inches are recommended for inframeous uses.

#### INTRAMUSCULAR ADMINISTRATION

intramissular injections should be made by directing the neerlie of suitable gauge and length into the flestly part of a thick muscle such as in the turnip, hip or thigh regions aword blood vessels and major nerves. Before injecting the solution publiback gently on the plunger of blood appears in the syringer, a blood vessel has been entered, withdraw the needle and select a different site. No more than 10 mus should be injected intamissicially all any one site in adult swine, rolate injection sites for each succeeding teatment. The volume administered per imjection site should be reduced according to age and body size so that 1 to 2 ml. per site is injected in small calves.

## SUBCUTANEOUS ADMINISTRATION

Subcutanensis injections in beel catific, dairy catific, and calves including preuminality (real) calves, should be made by directing the needle of switable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the up of the needle has prentiated the skin but is not lodged in muscle Before impecting the solution, pull back gently on the plunger if blood appears in the syringe, a blood vessel has been entered, which avit he needle and select a different site. The solitions should be impected slowly into the area between the skin and muscles. No more than 10 mit, should be impected subchaineously at any one site in adult beet and dairy catific, roles in injection sites for each succeeding treatment. The volume administered per impection site should be reduced according loane and hotyle sizes shill had men site is impected in small calves.

#### INTRAVENOUS ADMINISTRATION

MAXIM-200 (oxyletracycline injection) may be administered intravenously to beel and dairy callle. As with all highly concentrated materials, MAXIM-200 should be administered slowly by the intravenous route.

#### Preparation of the Animal for Injection

- Approximate location of vein The liquifar voin tuns in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of windpipe (See Fig. 1)

  Restraint A stanchion or chitle is ideal for restraining the
- 2 Restrant A stanchion or chule is ideal for restraining the animal With a halter, rone, or cattle leader (nose tongs) just the animals the halter rone, or cattle leader (nose tongs) until the consistency of the stanchion, called chule or post in such a maimer to flow at bew in the nock (See Fig. II) then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the ingular vein and make it easily accessible Catifion. Avoid restraining the animal with a light rope of halter around the throad or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.





Figure

3 Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

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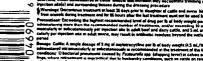
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■ PULL SLOWLY TO OPEN







989 79-4982-00-2 Made in USA

# Liquamycin® LA-200® (oxytetracycline myecton) Antibiotic

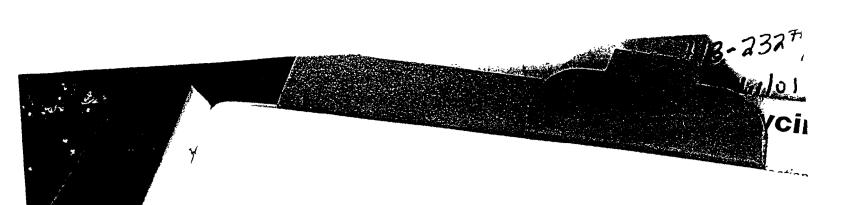
Each mL contains 200 mg oxytetracycline base as ai oxytetracycline

toryteae-yeane
For the treatment of disease in beef cattle, dairy cettle, calves, including preruminating (yeal) calves and swin for animal use only

# Net Contents: 100 mL

NADA #113 232, Approved by FDA





Liquanycin (A.200 (crystetracycline injection) is a sterile, preconstituted solution of the broad-spectrum ambibition expertacycline. Each mil contains 200 and of expertencycline base as amphotoco expetracycline. Each mil contains 200 and of expertencycline base as amphotoco expetracycline as wive base. 40,0%, 2-pyroledone, 5.0% pointenance and experimental experimen

Animal Health
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for the farmer for
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Liquamycin LA-200®

(oxytetracycline injection)

# Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline

For the treatment of disease in ru me treatment or disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Net Contents: 250 mL

NADA /113-232, Approved by FDA









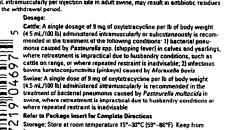
Liquamyon LA-200 (poytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each ml. contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and on a wive basis, 40 0% 2-pyrrolitione, 5.0% povidone, 1.3% anginesium oxyte, 0.2% sodium formaldelythe suitoxytele (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

CAUTION: Whine administered to cittle, muscle discoloration may necessitate trumming of the injection sitefal side surrounding lisases during the drassing procedure.

Warkings: Discontinue treatment at least 28 days prior to slaughter of cattle and sowne. Miki taken from animals during treatment and for 66 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest eccommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 ml. intramuscularly or subcutaneously per injection site in adult bed and daryc actile, and 5 ml. intramuscularly per injection site in adult swine, may result in ambiotic residues beyond the withdrawal period.

Dosage:



Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15\*-30\*C (59\*-86\*F) Keep from freezing

ON Restricted Drug (Celefornia)

Use Oaly as Directed

Not For Human Use

U.S. Patent No. 4,018,889

Amiral Health
from of 15341, USA
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NY NY 18017



The same of the sa

# Liquamycin®. LA-200®

(oxytetracycline injection)

## Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For the treatment of disease in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Net Contents: 500 mL

NADA #113-232, Approved by FOA



# Liquamycin® LA-200®

(oxytetracycline injection)

# Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline. For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

## Read Entire Package Insert Carefully Before Using This Product

Liquamycin LA-200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline (Terramycin®) by injection. Terramycin, discovered by Pfizer scientists, is an antimicrobial agent that is effective in the treatment of a wide range of diseases caused by susceptible grampositive and gram-negative bacteria.

Liquamycin LA-200 administered to cattle or swine for the treatment of bacterial pneumonia at an intramuscular dosage of 9 mg of oxytetracycline per lb of body weight has been demonstrated in clinical trials to be as effective as 2 or 3 repeated, daily treatments of Terramycin Injectable at 3-5 mg/lb of body weight.

Liquamycin LA-200 does not require refrigeration; however, it is recommended that it be stored at room temperature, 15°-30°C (59°-86°F). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.



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WARNINGS: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

PRECAUTIONS: Exceeding the highest recommended dosage level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Reactions of an allergic or anaphylactic nature, sometimes fatal, have been known to occur in hypersensitive animals following the injection of oxytetracycline. Such adverse reactions can be characterized by signs such as restlessness, erection of hair, muscle trembling; swelling of eyelids, ears, muzzle, anus, and vulva (or scrotum and sheath in males); labored breathing, defecation and urination, glassy-eyed appearance, eruption of skin plaques, frothing from the mouth, and prostration. Pregnant animals that recover may subsequently abort. At the first sign of any adverse reaction, discontinue use of this product and administer epinephrine at the recommended dosage levels. Call a veterinarian immediately.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that Liquamycin LA-200 be administered slowly by this route.

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Liquamycin LA-200 in conjunction with penicillin.

STORAGE: Store at room temperature 15°-30°C (59°-86°F). Keep from freezing.

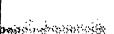
CARE OF SICK ANIMALS: The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with Liquamycin LA-200 show a noticeable improvement within 24-48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs, and needless losses. Good housing, sanitation, and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

INDICATIONS: Liquamycin LA-200 is intended for use in the treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (yeal) calves; and swine when due to oxytetracycline-susceptible organisms:

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INDICATIONS: Liquamycin LA-200 is intended for use in the treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

Cattle: Liquamycin LA-200 is indicated in the treatment of pneumonia and shipping fever complex associated with Pasteurella spp. and Hemophilus spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by Moraxella bovis; foot rot and diphtheria caused by Fusobacterium necrophorum; bacterial enteritis (scours) caused by Escherichia coli; wooden tongue caused by Actinobacillus lignieresii; leptospirosis caused by Leptospira pomona; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine: Liquamycin LA-200 is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*.

In sows, Liquamycin LA-200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by Escherichia coli.

#### DOSAGE:

Cattle: Liquamycin LA-200 is to be administered by intramuscular, subcutaneous, or intravenous injection to beef cattle; dairy cattle; and calves, including preruminating (yeal) calves.

A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Liquamycin LA-200 can also be administered by intravenous, subcutaneous, or intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg/lb of body weight per day is recommended. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

**Swine:** A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered *intramuscularly* is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Liquamycin LA-200 can also be administered by intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 mg of oxytetracycline per lb of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, Liquamycin LA-200 should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

9 mg/lb Dosage Volume of Undiluted Liquamycin LA-200 3 or 5 mg/lb Dosage Volume of Diluted Liquamycin LA-200

Body 5 lb

0.2 mL

0.6 mL

1:7

1.0 mL

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DIRECTIONS FOR USE: Liquamycin LA-200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, Liquamycin LA-200 should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with suitable disinfectant, such as 70% alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16–18 gauge and 1–1½ inches long are adequate for intramuscular and subcutaneous injections. Needles 2–3 inches are recommended for intravenous use.

#### Intramuscular Administration:

Intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle such as in the rump, hip, or thigh regions; avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. No more than 10 mL should be injected intramuscularly at any one site in adult beef and dairy cattle, and not more than 5 mL per site in adult swine; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1–2 mL per site is injected in small calves.

# Subcutaneous Administration:

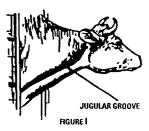
Subcutaneous injections in beef cattle, dairy cattle, and calves, including preruminating (veal) calves, should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has penetrated the skin but is not lodged in muscle. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. The solution should be injected slowly into the area between the skin and muscles. No more than 10 mL should be injected subcutaneously at any one site in adult beef and dairy cattle; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1–2 mL per site is injected in small calves.

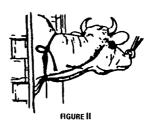
## Intravenous Administration:

Liquamycin LA-200 may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Liquamycin LA-200 should be administered *slowly* by the intravenous route.

## Preparation of the Animal for Injection:

- 1. Approximate location of vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of the windpipe (see Fig. I).
- 2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute, or post in such a manner to form a bow in the neck (see Fig. II), then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the jugular vein and make it easily accessible. Caution: Avoid restraining the animal with a tight rope or halter around the throat or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.
- 3. Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.





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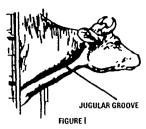
#### Entering the Vein and Making the Injection:

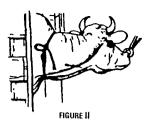
1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (see Fig. II). In thicknecked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the heart. Under ordinary conditions it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can be easily seen and felt in thin-necked animals. As a further check in identifying the vein, tap it with the fingers in front of the choke rope. Pulsations that



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2. Inserting the needle. This involves 3 distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require 2 or 3 attempts before the vein is entered. The vein has a tendency to roll away from the point of the needle, especially if the needle is not sharp. The vein can be steadied with the thumb and finger of one hand. With the other hand, the needle point is placed directly over the vein, slanting it so that its direction is along the length of the vein, either toward the head or toward the heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates that the vein has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the hub, exercising caution to see that the needle does not penetrate the opposite side of the vein. Continuous steady flow of blood through the needle indicates that the needle is still in the vein. If blood does not flow continuously, the needle is out of the vein (or clogged) and another attempt must be made. If difficulty is encountered, it may be advisable to use the vein on the other side of the neck.

3. While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that the injection can be started without delay after the vein has been entered.

4. Making the injection. With the needle in position as indicated by continuous flow of blood, release the choke rope by a quick pull on the free end. This is essential—the medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing Liquamycin LA-200 to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates that the needle has slipped out of the vein (or is clogged) and the procedure will have to be repeated. Watch for any swelling under the skin near the needle, which would indicate that the medication is not going into the vein. Should this occur, it is best to try the vein on the opposite side of the neck.

5. Removing the needle. When injection is complete, remove needle with straight pull. Then apply pressure over area of injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

Restricted Drug (California)— Use Only as Directed

Not For Human Use

NADA #113-232, Approved by FDA





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Animal Health

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